



Steroids, Topical

Therapeutic Class Review (TCR)

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FDA-APPROVED INDICATIONS

Drug	Manufacturer	Indications
Low Potency		
alclometasone dipropionate (Aclovate®) ¹	generic, PharmaDerm	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
desonide (Desonate®) ²	Bayer	Treatment of mild to moderate atopic dermatitis
desonide (Desowen®) ³	generic, Galderma	
desonide (Verdeso™) ⁴	Stiefel	
fluocinolone acetonide (Capex® Shampoo) ⁵	Galderma	Treatment of seborrheic dermatitis of the scalp
fluocinolone acetonide (Derma-Smoothe/FS®) ^{6,7}	generic, Hill Derm	Body oil: treatment of atopic dermatitis in adults; moderate to severe atopic dermatitis in patients three months and older for up to 4 weeks Scalp oil: treatment of psoriasis of the scalp in adult patients
fluocinolone acetonide (Synalar®) ⁸	generic, Medimetriks	Relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
hydrocortisone (Ala-Cort®, Ala-Scalp®, Aqua Glycolic HC®, Balneol for Her®, Caldecort®, NuZon™, Scalacort®, Scalacort-DK® Kit, Texacort®, PEDIADERM™ HC) ^{9,10,11}	generic, Avidas, Arbor, Mission	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
Medium Potency		
betamethasone valerate (Luxiq®) ¹²	generic, Stiefel	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses of the scalp
betamethasone valerate ¹³	generic	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
clocortolone pivalate (Cloderm®) ¹⁴	Promius	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
fluocinolone acetonide (Synalar®) ¹⁵	generic, Medimetriks	Cutivate Cream: Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses and atopic dermatitis
flurandrenolide (Cordran®) ¹⁶	Aqua	Cutivate Lotion: Relief of the inflammatory and pruritic manifestations of atopic dermatitis
flurandrenolide (Cordran® Tape) ¹⁷	Watson	Locoid/Lipocream: Treatment of mild to moderate atopic dermatitis in patients 3 months to 18 years of age
fluticasone propionate (Cutivate®) ¹⁸	generic, PharmaDerm	
hydrocortisone butyrate (Locoid® / Lipocream) ¹⁹	generic, Triax	
hydrocortisone probutate (Pandel®) ²⁰	PharmaDerm	
hydrocortisone valerate (Westcort®) ²¹	generic, Ranbaxy	Cream, Ointment: Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses in adult patients

FDA-Approved Indications (continued)

Drug	Manufacturer	Indications
Medium Potency (continued)		
mometasone furoate (Elocon®) ²²	generic, Merck	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
mometasone furoate (Momexin™) ²³	JSJ	
prednicarbate (Dermatop®) ²⁴	generic, Valeant	
High Potency		
amcinonide ²⁵	generic	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses Topicort Topical Spray: Only approved for treatment of plaque psoriasis in patients 18 years of age or older
betamethasone dipropionate ²⁶	generic	
desoximetasone (Topicort®) ²⁷	generic, Taro	
desoximetasone (Topicort® Topical Spray) ²⁸	Taro	
diflorasone diacetate (Apexicon/Apexicon E)	generic, PharmaDerm	
fluocinonide ²⁹	generic	
fluocinonide (Vanos™) ³⁰	Medicis	
halcinonide (Halog®) ³¹	Ranbaxy	
triamcinolone acetonide (Kenalog®, Triderm®) ³²	generic, Ranbaxy, Crown Labs	
Very High Potency		
betamethasone dipropionate augmented (Diprolene® AF) ³³	generic, Merck	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
clobetasol propionate (Clobex®) ³⁴	generic, Galderma	Lotion: Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses Shampoo: Treatment of moderate to severe forms of scalp psoriasis Spray: Treatment of moderate to severe plaque psoriasis affecting up to 20 percent of body surface area
clobetasol propionate (Cormax®, Temovate/Temovate E®) ^{35,36,37}	generic, ECR Pharmaceuticals, PharmaDerm	Cream, gel, ointment: Short-term treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses Solution: Short-term treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses of the scalp
clobetasol propionate (Olux® / -E, Olux®-Olux-E Complete Pack) ³⁸	generic, Stiefel	Short-term treatment of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses of the scalp and short-term treatment of mild to moderate plaque psoriasis of non-scalp regions
halobetasol propionate (Halac Kit) ³⁹	Acella	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses
halobetasol propionate (Ultravate®) ⁴⁰	generic, Ranbaxy	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses

FDA-Approved Indications (continued)

Drug	Manufacturer	Indications
Very High Potency (continued)		
halobetasol propionate (Ultravate® PAC Kit, Ultravate® X) ⁴¹	generic	Relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses

OVERVIEW

Topical corticosteroids are used for a variety of inflammatory skin conditions.

Atopic dermatitis (AD) is a chronic, inflammatory dermatologic condition. The skin becomes pruritic and inflamed, causing swelling, cracking, weeping, crusting, and scaling. AD is often referred to as "eczema." It commonly occurs in patients affected by asthma and/or allergic rhinitis and is associated with elevated serum IgE levels. Usually diagnosed before the age of five years, AD can occur at any age.

Psoriasis is another inflammatory skin condition. Plaque psoriasis is the most common type which appears as patches of raised, reddish skin covered by silvery-white scale. These patches, or plaques, frequently form on the elbows, knees, lower back, and scalp. Controlling the signs and symptoms typically requires lifelong therapy.

Seborrheic dermatitis is an inflammatory disorder affecting areas of the head and trunk, where sebaceous glands are most prominent. Scalp seborrhea varies from mild dandruff to dense scale, while facial and trunk seborrhea is characterized by powdery or greasy scale in skin folds and along hair margins.

Pharmacotherapy choices for these conditions typically include emollients and topical corticosteroids.⁴² Emollients remain the cornerstone of any AD pharmacotherapeutic regimen; they restore the skin barrier function. Topical corticosteroids are the standard of care to which other treatments are compared. The selected medication and potency should depend on medication efficacy then severity of disease, location and surface area of affected skin, intended duration of treatment, medication vehicle, patient preference, and the age of the patient. In short-term durations of treatment, high potency medications have greater efficacy when compared to less potent medications. However, highly potent topical corticosteroids do have an increased risk in side effects. Dermatologic effects such as striae, atrophy, and tachyphylaxis, as well as potential non-dermatologic effects on linear growth rate, bone density, and hypothalamic-pituitary-adrenal (HPA) axis suppression limit the long-term use of these agents. Additionally, the increased incidences of adverse dermatologic effects are positively correlated with the medication's frequency and duration of use. The true efficacy and risk of long-term topical corticosteroid use is unknown due to most clinical trials only involving short-term studies. Furthermore, it is recommended that continued therapy be supervised by the prescriber and once a clinical response is demonstrated a gradual reduction in utilization is appropriate.⁴³ Non-pharmacologic therapies such as irritant avoidance and dietary intervention have also been recommended, but these measures have not demonstrated consistent, beneficial results.

PHARMACOLOGY⁴⁴

Topical corticosteroids mimic compounds that are secreted by the adrenal cortex. Their anti-inflammatory, antipruritic, and vasoconstrictive effects make them effective treatments in dermatological conditions. The exact mechanisms of action for the topical corticosteroids are not completely understood. Corticosteroids are thought to induce phospholipase A2 inhibitory proteins, or lipocortins, which control the biosynthesis of mediators of inflammation, such as prostaglandins and leukotrienes, by inhibiting the release of arachadonic acid. Substitution of a fluorine atom, an acetone group, omission of the hydroxyl group, or esterification of a hydroxyl group in certain positions on the cortisol molecule increases anti-inflammatory activity. Based on this, corticosteroids are classified by potency. In this review, low, medium, high, and very high classifications are used to differentiate among the corticosteroids.

PHARMACOKINETICS^{45,46}

The extent of topical absorption of corticosteroids is dependent on factors such as drug vehicle, skin integrity, use of occlusive dressings, use of more potent corticosteroids, use over large areas, and prolonged use. Areas where the stratum corneum is thin, such as the eyelids, genitalia, and face, also increase the risk for further absorption. The presence of skin disease processes, such as inflammation, may increase cutaneous absorption. Systemically absorbed corticosteroids are metabolized in the liver primarily, and excreted by the kidneys. Some corticosteroids and their metabolites are excreted into the bile.

CONTRAINDICATIONS/WARNINGS^{47,48,49,50,51,52,53,54,55,56,57,58,59,60,61,62,63,64,65,66,67,68,69,70,71,72,73,74,75}

Corticosteroids are contraindicated in patients who have known hypersensitivities to any active or inactive ingredient in their prescribed preparation.

HPA axis suppression, manifestations of Cushing's syndrome (high blood levels of cortisol), hyperglycemia, glucosuria, and growth retardation in children can result from the systemic absorption of topical corticosteroids. If these effects are seen the medications should be discontinued, applied less frequently, or substituted for a less potent topical corticosteroid. Patients who apply corticosteroids to a large surface area should periodically be evaluated by cortisol or ACTH stimulation tests. Recovery of the HPA axis is generally prompt and complete upon discontinuation of the corticosteroid.

Topical corticosteroids should not be used in the treatment of rosacea or perioral dermatitis. They also should not be used on the face, groin, or in the axillae because those areas are more prone to atrophic changes during corticosteroid therapy. Increased intraocular pressure, cataracts, and glaucoma have been reported in patients who use topical corticosteroids near the eyes. Topical corticosteroids should be discontinued if irritation develops.

Fluocinolone acetonide (Derma-Smoother/FS) contains 48 percent refined peanut oil NF and should be used with caution in peanut-sensitive patients. Therapy should be immediately discontinued if signs of hypersensitivity are present, or disease exacerbations occur.

Betamethasone dipropionate (Diprolene/AF), clobetasol propionate (Temovate), fluocinonide (Vanos), and halobetasol propionate (Ultravate and Halonate) should not be used in perioral dermatitis or rosacea.

DRUG INTERACTIONS⁷⁶

When appropriate, antifungals or antibacterials should be applied to dermatological infections. If a response is not seen in a reasonable amount of time, specific to the drug being used, the topical corticosteroid should be discontinued until the infection is controlled.

ADVERSE EFFECTS

Drug	Burning	Dryness	Folliculitis	Itching	Irritation
Low Potency					
alclometasone dipropionate (Aclovate) ⁷⁷	1-2	2	nr	1-2	2
desonide (Desonate) ⁷⁸	1	nr	nr	<1	nr
desonide (Desowen) ⁷⁹	reported	nr	nr	reported	reported
desonide (Verdeso) ⁸⁰	3	nr	nr	nr	reported
fluocinolone acetonide (Capex Shampoo) ⁸¹	nr	nr	nr	nr	nr
fluocinolone acetonide (Derma-Smoothe/FS) ^{82, 83}	5 (body oil) 5.2 (scalp oil)	nr	2 (body oil) 1.7 (scalp oil)	5 (body oil) 5.2 (scalp oil)	5 (body oil) 5.2 (scalp oil)
hydrocortisone (Ala-Cort, Caldecort, Ala-Scalp, Aqua Glycol HC®, Balneol for Her®, Scalacort, Scalacort-DK Kit, Texacort, PEDIADERM HC) ^{84,85,86}	reported	reported	reported	reported	reported

Adverse effects data are reported as percentages and are obtained from prescribing information, therefore should not be considered comparative data or all-inclusive. nr = not reported

Drug	Burning	Dryness	Folliculitis	Itching	Irritation
Medium Potency					
betamethasone valerate (Luxiq) ⁸⁷	2-44	reported	reported	2-44	reported
betamethasone valerate (Beta-Val) ⁸⁸	reported	reported	reported	reported	reported
clocortolone pivalate (Cloderm) ⁸⁹	reported	reported	reported	reported	reported
fluocinolone acetonide ⁹⁰	reported	reported	reported	reported	reported
flurandrenolide (Cordran) ⁹¹	reported	reported	reported	reported	reported
flurandrenolide (Cordran Tape) ⁹²	reported	reported	reported	reported	reported
fluticasone propionate (Cutivate) ⁹³	0.6-2	0.5-7	0.5-1	1-2.9	1-2.9
hydrocortisone butyrate (Locoid / Lipocream) ⁹⁴	nr	nr	nr	2	1
hydrocortisone probutate (Pandel) ⁹⁵	<1	reported	reported	reported	reported
hydrocortisone valerate (Westcort) ⁹⁶	reported	2	reported	2-6	1
mometasone furoate (Elocon) ⁹⁷	1.6	nr	nr	1.6	nr
mometasone furoate (Momexin) ⁹⁸	reported	reported	1	reported	reported
prednicarbate (Dermatop) ⁹⁹	reported	reported	reported	reported	reported

Adverse effects data are reported as percentages and are obtained from prescribing information, therefore should not be considered comparative data or all-inclusive. nr = not reported

Adverse Effects (continued)

Drug	Burning	Dryness	Folliculitis	Itching	Irritation
High Potency					
amcinonide (Cyclocort) ¹⁰⁰	reported	reported	reported	reported	reported
betamethasone dipropionate ¹⁰¹	reported	reported	reported	reported	reported
desoximetasone (Topicort) ¹⁰²	<1	reported	<1	reported	reported
desoximetasone (Topicort Topical Spray) ¹⁰³	nr	2.7	<1	2	2.7
diflorasone diacetate ¹⁰⁴	nr	nr	nr	nr	nr
fluocinonide ¹⁰⁵	nr	nr	reported	reported	nr
fluocinonide (Vanos) ¹⁰⁶	1.8-2.3	reported	nr	reported	reported
halcinonide (Halog) ¹⁰⁷	nr	nr	nr	nr	nr
triamcinolone acetonide (Kenalog, Triderm) ¹⁰⁸	reported	nr	reported	reported	reported

Adverse effects data are reported as percentages and are obtained from prescribing information, therefore should not be considered comparative data or all-inclusive. nr = not reported

Drug	Burning	Dryness	Folliculitis	Itching	Irritation
Very High Potency					
betamethasone dipropionate augmented (Diprolene AF) ¹⁰⁹	reported	reported	<1	<1	reported
clobetasol propionate (Clobex) ¹¹⁰	reported; 40 (spray)	1-2	reported	0.5-3	1
clobetasol propionate (Cormax, Temovate/Temovate E) ^{111,112, 113}	0.5-10	reported	<2	<2	<2
clobetasol propionate (Olux / -E, Olux®-Olux-E Complete Pack) ¹¹⁴	10	<1	nr	<2	<2
halobetasol propionate (Halonate) ¹¹⁵	1.6	reported	reported	reported	nr
halobetasol propionate (Ultravate) ¹¹⁶	1.6-4.4	reported	reported	4.4	nr

Adverse effects data are reported as percentages and are obtained from prescribing information, therefore should not be considered comparative data or all-inclusive. nr = not reported

Local adverse effects occur more frequently with the use of occlusive dressings.

Adverse effects that are reported with the general use of topical corticosteroids and may occur more frequently with the use of occlusive dressings also include burning, itching, irritation, dryness, folliculitis, hypertrichosis, perioral dermatitis, allergic contact dermatitis, hypertrichosis, acneiform eruptions, hypopigmentation, secondary infection, skin atrophy, striae, and miliaria. While product-specific adverse event rates may not be available, these events are known to occur with topical corticosteroids.

Corticosteroids in gel formulations can cause dryness and irritation to the skin. Their use is usually limited to the scalp and beard areas.

Halobetasol propionate (Halac Kit) does not have adverse event data available.¹¹⁷

SPECIAL POPULATIONS^{118,119,120,121,122,123,124,125,126,127,128,129,130,131,132,133,134,135,136,137,138,139,140,141,142,143,144,145,146,147,148}

Pediatric patients may be susceptible to higher incidences of corticosteroid-induced HPA axis suppression, Cushing's syndrome, and increased intracranial pressure because of a larger skin surface area: body weight ratio.

Pediatric Age	Drug
> 3 months	desonide (Desonate, Verdeso); flucinolone acetonide (Derma-Smoothe/FS body oil); fluticasone (Cutivate) cream; hydrocortisone butyrate (Locoid/ Lipocream)
≥ 1 year	alclometasone (Aclovate); fluticasone (Cutivate) lotion
≥ 2 years	mometasone (Elocon, Momexin)
≥ 12 years	fluocinonide (Vanos); halobetasol (Ultravate, Halonate); clobetasol (Temovate, Olux, Cormax)
≥ 13 years	betamethasone dipropionate (Diprolene AF)
≥ 18 years	clobetasol propionate (Clobex); flucinolone acetonide (Derma-Smoothe/FS scalp oil); fluticasone (Cutivate) lotion; hydrocortisone probutate (Pandel); hydrocortisone valerate (Westcort)

Safety and efficacy of mometasone furoate 0.1% cream in children (greater than two years old) beyond three weeks have not been established. Clodortolone (Cloderm), desoximetasone (Topicort, Topicort Topical Spray), and flurandrenolide (Cordran/SP and tape) use should be limited to the least amount compatible with an effective therapeutic regimen. Hydrocortisone butyrate (Locoid/Lipocream) is not approved for pediatric use with the corticosteroid-dermatoses indication. The safety and effectiveness of all other products have not been established in pediatric patients.

A randomized, double-blind study compared the efficacy of hydrocortisone butyrate 0.1% cream with hydrocortisone 1% cream in 40 children suffering from atopic dermatitis.¹⁴⁹ The medications were applied twice daily for a maximum of four weeks. Complete clearance of skin symptoms was found in 36 percent of the hydrocortisone butyrate patients and in 23 percent of the hydrocortisone patients following two weeks of therapy and in 60 and 30 percent, respectively, after four weeks of treatment, a statistically significant difference. No serious adverse events were reported during the study.

Two randomized, parallel-group, double-blind studies in children ages two to 14 years old evaluated fluticasone propionate 0.05% cream with either hydrocortisone 1% cream (n=137) or hydrocortisone butyrate 0.1% cream (n=129) for both acute and maintenance treatment of moderate to severe atopic dermatitis.¹⁵⁰ Treatments were applied twice daily for two to four weeks, and thereafter as needed for up to 12 weeks. The primary outcome measure, Total Atopic Dermatitis Score, showed improvement in disease severity following treatment with fluticasone propionate compared with either hydrocortisone or hydrocortisone butyrate for acute treatment (p<0.001 versus hydrocortisone; p=0.042 versus hydrocortisone butyrate) and maintenance treatment (p=0.006 versus hydrocortisone; p=0.042 versus hydrocortisone butyrate). In both studies, treatments were equally well tolerated with no visible signs of skin atrophy.

In a double-blind, parallel-group trial, alclometasone dipropionate 0.05% cream or hydrocortisone butyrate 0.1% cream were applied twice daily for two weeks to 40 children (five to 11 years old) with

atopic dermatitis.¹⁵¹ Improvement in erythema, induration, and pruritus averaged 76 percent for alclometasone dipropionate and 70 percent for hydrocortisone butyrate. Two patients in the alclometasone dipropionate group and one in the hydrocortisone butyrate group reported mild stinging.

Pregnancy

All topical corticosteroid products are Pregnancy Category C.

DOSAGES¹⁵²

Drug	Dose	Dosage forms
Low Potency		
alclometasone dipropionate (Aclovate)	Apply to affected skin two or three times daily; treatment should be limited to three weeks	0.05% cream, ointment
desonide (Desonate)	Apply to affected skin twice daily; treatment should not exceed four weeks (Verdeso, Desonate) Desonide cream and ointment can be applied two to four times daily and the lotion can be applied two to three times daily	0.05% gel
desonide (Desowen)		0.05% cream, lotion, ointment
desonide (Verdeso)		0.05% foam
fluocinolone acetonide (Capex Shampoo)	Apply one ounce to scalp daily for five minutes, then rinse	0.01% shampoo
fluocinolone acetonide (Derma-Smoothe/FS) ^{153, 154}	Body oil: Adults: Apply thin film to the affected areas three times daily Pediatric: Apply thin film to moistened skin twice daily for up to four weeks Scalp oil: Dampen hair and then apply to scalp and cover overnight or a minimum of four hours before washing off	0.01% body oil 0.01% scalp oil
fluocinolone acetonide (Synalar) ¹⁵⁵	Applied to the affected skin as a thin film from two to four times daily depending on the severity of the condition.	0.01% solution 0.01% solution kit (60 mL fluocinolone acetonide 0.01% topical solution and 454 grams Rehyla™ Hair & Body Cleanser) (Synalar Solution Kit)
hydrocortisone (Ala-Cort, Caldecort, Ala-Scalp, Aqua Glycol HC®, Balneol for Her®, Scalacort, Scalacort-DK Kit, Texacort, Pediaderm HC Complete Kit)	Apply to affected skin two to four times daily	0.25% lotion 1% cream, gel, lotion, ointment 2% gel, lotion 2.5% cream, lotion, ointment, solution Pediaderm HC 2% Complete Kit comes with a protective emollient lotion tube

Dosages (continued)

Drug	Dose	Dosage forms
Medium Potency		
betamethasone valerate (Luxiq)	Apply to scalp twice daily; occlusive dressings should not be used unless directed by physician	0.12% foam
betamethasone valerate (Beta-Val)	Apply to affected skin two to four times daily	0.1% cream, lotion, ointment
fluocinolone acetonide (Synalar) 156	Apply to affected skin two to four times daily	0.025% cream, ointment, cream kit (120 grams fluocinolone acetonide 0.025% topical cream and 255 grams Keradan™ Cream) (Synalar Cream Kit), ointment kit (120 grams fluocinolone acetonide 0.025% topical ointment and 255 grams Keradan™ Cream) (Synalar Ointment Kit)
flurandrenolide (Cordran)	Lotion: Apply to affected skin two to three times daily Cream: Apply to affected skin one to four times daily	0.05% lotion 0.05% cream (Cordran SP)
flurandrenolide (Cordran Tape)	Apply tape to affected skin every 12-24 hours	4 mcg/cm2 tape
fluticasone propionate (Cutivate)	Ointment: Apply to affected skin twice daily Cream: Apply to affected skin once or twice daily Lotion: Apply to affected skin once daily Treatment should be limited to four weeks	0.005% ointment 0.05% cream 0.05% lotion
hydrocortisone butyrate (Locoid / Lipocream)	Apply to affected skin two to three times daily; treatment should be limited to two weeks	0.1% cream, solution, ointment, lotion
hydrocortisone probutate (Pandel)	Apply to affected skin once or twice daily; if no improvement is seen within two weeks, reassessment of diagnosis may be necessary	0.1% cream
hydrocortisone valerate (Westcort)	Apply to affected skin two to three times daily; occlusive dressings should not be used unless directed by a physician	0.2% ointment 0.2% cream (generic only)
mometasone furoate (Elocon)	Apply to affected skin once daily; treatment should be limited to three weeks	0.1% cream, lotion, ointment
mometasone furoate (Momexin)	Apply to affected skin once daily; if no improvement is seen within two weeks, reassessment of diagnosis may be necessary; occlusive dressings should not be used	0.1% cream (co-packaged with ammonium lactate 12% mousse)
prednicarbate (Dermatop)	Apply to affected skin twice daily	0.1% cream, ointment

Dosages (continued)

Drug	Dose	Dosage forms
High Potency		
amcinonide (Cyclocort)	Apply to affected skin two to three times daily	0.1% cream, lotion, ointment
betamethasone dipropionate	Apply to affected skin once to twice daily	0.05% cream, lotion, ointment
desoximetasone (Topicort)	Apply to affected skin twice daily	0.05% cream, gel, ointment 0.25% cream, ointment
desoximetasone (Topicort Topical Spray) ¹⁵⁷	Plaque psoriasis: apply as a thin film to the affected skin twice daily; rub in gently; occlusive dressings should not be used unless directed by a physician. Treatment beyond four weeks is not recommended.	0.25% spray
diflorasone diacetate (Apexicon/Apexicon E)	Apply to affected skin twice daily	0.05% cream, ointment 0.05% cream (Apexicon E), 0.05% ointment (Apexicon)
fluocinonide	Apply to affected skin one to four times daily	0.05% cream, gel, ointment, solution
fluocinonide (Vanos)	Apply to affected skin once or twice daily; total dose should not exceed 60 g per week; treatment should be limited to two weeks	0.1% cream
halcinonide (Halog)	Apply to affected skin one to three times daily	0.1% cream, ointment
triamcinolone acetonide (Kenalog, Triderm)	Apply to affected skin two to four times daily	0.025% cream, lotion, ointment 0.05% ointment 0.05% Trianex ointment 0.1% cream, lotion, ointment 0.5% cream, ointment 0.147 gm/1 gm topical spray

Dosages (continued)

Drug	Dose	Dosage forms
Very High Potency		
betamethasone dipropionate augmented (Diprolene AF)	Apply to affected skin once or twice daily; total dose should not exceed 50 g or mL per week; treatment should be limited to two weeks; occlusive dressings should not be used	0.05% cream, gel, lotion, ointment
clobetasol propionate (Clobex)	Apply lotion or spray to affected skin twice daily; total dose should not exceed 50 g or 1.75 ounces per week; treatment should be limited to two weeks (four weeks for moderate to severe plaque psoriasis); apply shampoo to dry scalp once daily and rinse after 15 minutes	0.05% lotion, shampoo, spray
clobetasol propionate (Cormax, Temovate/Temovate E)	Apply to affected skin twice daily; total dose should not exceed 50 g or mL per week; treatment should be limited to two weeks	0.05% cream, gel, ointment, solution 0.05% cream (Temovate E)
clobetasol propionate (Olux / -E, Olux-Olux-E Complete Pack)	Apply to affected skin twice daily; total dose should not exceed 50 g per week; treatment should be limited to two weeks	0.05% foam
halobetasol propionate (Halac Kit)	Apply to affected skin once or twice daily; total dose should not exceed 50 g per week; treatment should be limited to two weeks	Halac Kit is a 0.05% ointment (packaged with a bottle of 12% ammonium lactate topical lotion)
halobetasol propionate (Ultravate, Halonate)	Apply to affected skin once or twice daily; total dose should not exceed 50 g per week; treatment should be limited to two weeks; occlusive dressings should not be used	0.05% cream, ointment Halonate is a 0.05% ointment (packaged with a can of 12% ammonium lactate mousse)
halobetasol propionate (Ultravate PAC Kit, Ultravate X)	Apply to affected skin once or twice daily; total dose should not exceed 50 g per week; treatment should be limited to two weeks; occlusive dressings should not be used	Ultravate PAC Kit 0.05% cream, ointment (packaged with a bottle of ammonium lactate 12% topical lotion) Ultravate X 0.05% cream, ointment (packaged with a tube of 10% ammonium lactate topical cream)

Once atopic dermatitis is stabilized with daily treatment, studies have shown that intermittent therapy with more potent topical corticosteroids can be as effective as daily therapy with a mild topical corticosteroid.^{158,159} During intermittent treatment, use of emollients is recommended on days that steroids are not applied.

CLINICAL TRIALS**Search Strategy**

Articles were identified through searches performed on PubMed and review of information sent by manufacturers. Search strategy included the FDA-approved use of all drugs in this class. Randomized, controlled, comparative trials are considered the most relevant in this category. Studies included for analysis in the review were published in English, performed with human participants and randomly allocated participants to comparison groups. In addition, studies must contain clearly stated, predetermined outcome measure(s) of known or probable clinical importance, use data analysis

techniques consistent with the study question and include follow-up (endpoint assessment) of at least 80 percent of participants entering the investigation. Despite some inherent bias found in all studies including those sponsored and/or funded by pharmaceutical manufacturers, the studies in this therapeutic class review were determined to have results or conclusions that do not suggest systematic error in their experimental study design. While the potential influence of manufacturer sponsorship/funding must be considered, the studies in this review have also been evaluated for validity and importance.

clobetasol propionate (Cormax, Temovate) and betamethasone dipropionate (Diprolene)

A double-blind study compared the effectiveness of clobetasol propionate 0.05% ointment and betamethasone dipropionate 0.05% ointment twice daily in 130 patients with moderate to severe signs of psoriasis for two weeks.¹⁶⁰ Both drugs were well tolerated. Significantly more patients showed greater improvement when treated with clobetasol propionate. Follow-up evaluation two weeks after the treatment period showed longer remissions with clobetasol propionate use ($p < 0.001$).

fluocinolone acetonide (Synalar) and betamethasone dipropionate (Diprolene)

In a double-blind, randomized study, 62 patients with psoriasis or eczema were treated with betamethasone dipropionate 0.05% cream or fluocinolone acetonide 0.025% cream twice daily for three weeks.¹⁶¹ Both preparations were effective, well tolerated, and cosmetically acceptable. Of the patients treated with betamethasone dipropionate, 57 percent were rated as being “much better” in the overall assessment of response at the end of the trial period compared to only 25 percent of fluocinolone acetonide patients.

fluticasone propionate (Cutivate) and betamethasone dipropionate (Diprolene)

A randomized, double-blind, parallel-group study compared the safety, tolerability, and efficacy of fluticasone propionate 0.005% ointment and betamethasone dipropionate 0.05% ointment twice daily in 92 patients with moderate to severe eczema.¹⁶² Statistically significant improvement in the severity of signs and symptoms was found as early as two weeks following treatment initiation in both groups. There was no significant difference between the treatments following two or four weeks of therapy with regard to almost all efficacy variables. Both treatments were well tolerated and showed minimal suppression of the HPA axis as evidenced by morning plasma cortisol concentration determinations.

The efficacy, safety, and tolerability of fluticasone propionate 0.005% ointment and betamethasone dipropionate 0.05% ointment were compared in a 12-week, randomized, double-blind, parallel-group study of 74 patients with moderate to severe psoriasis.¹⁶³ Fluticasone propionate was not significantly different from betamethasone dipropionate at day 15 ($p = 0.147$), at the end of treatment analysis ($p = 0.245$), or after four weeks ($p = 0.154$). Neither medication resulted in any abnormal laboratory values, including plasma cortisol levels, over the twelve-week safety study period. Both medications were well tolerated.

fluticasone propionate (Cutivate) and hydrocortisone butyrate (Locoid)

In a randomized, double-blind, parallel-group study involving 120 patients, the safety and tolerability of fluticasone propionate 0.05% cream and hydrocortisone butyrate 0.1% cream in the treatment of moderate to severe eczema were compared.¹⁶⁴ Fluticasone propionate was found to be similar in

efficacy to hydrocortisone butyrate after four weeks. One hydrocortisone butyrate patient's eczema was severely exacerbated by drug therapy over the 12-week safety study, but the drugs were otherwise well tolerated. Plasma cortisol monitoring, revealed minimal HPA axis suppression.

The efficacy and safety of fluticasone propionate 0.005% ointment and hydrocortisone butyrate 0.1% ointment twice daily were compared in 113 adult patients with moderate to severe psoriasis in a double-blind, randomized, parallel study.¹⁶⁵ Efficacy assessments were made at weekly intervals for up to four weeks. Fluticasone propionate was found to be therapeutically superior to hydrocortisone butyrate, as well as safe and well tolerated. Its onset of action was rapid, and no systemic adverse effects occurred.

halobetasol propionate (Ultravate) and betamethasone dipropionate (Diprolene)

In a double-blind, parallel-group, comparative trial, 104 patients with severe, localized plaque psoriasis were given halobetasol propionate 0.05% ointment or betamethasone dipropionate 0.05% ointment.¹⁶⁶ Halobetasol dipropionate demonstrated an 88.7 percent success rate assessed as "healed" or "marked improvement" compared to 78.5 percent for betamethasone dipropionate ointment. Healing was observed within 24 days of the start of treatment in 40 percent and 25 percent of the patients who received halobetasol propionate and betamethasone dipropionate ointments, respectively. Tolerability was acceptable for both agents after four weeks of treatment. Patients preferred halobetasol propionate ointment over betamethasone dipropionate ointment based on cosmetic acceptability and ease of application.

halobetasol propionate (Ultravate), clobetasol dipropionate (Cormax, Temovate), and betamethasone dipropionate (Diprolene)

In two double-blind, parallel-group, multicenter trials, halobetasol propionate 0.05% cream was compared with clobetasol propionate 0.05% cream and betamethasone dipropionate 0.05% cream in 264 patients with acute severe exacerbations of atopic dermatitis.¹⁶⁷ The efficacy of halobetasol propionate and betamethasone dipropionate was similar with regard to the success rate, as indicated by ratings of "healed" and "marked improvement" (88 versus 90 percent, respectively) and by an onset of therapeutic effect within three days of the start of treatment (40 versus 39 percent). The efficacy of halobetasol propionate and clobetasol propionate was also similar with regard to success rates (89 versus 93 percent, respectively) and an onset of therapeutic effect within three days of the start of treatment (41 versus 38 percent). Dryness of the skin and itching at the site of application were the reported adverse effects, but the creams were all well tolerated.

halobetasol propionate (Ultravate) and betamethasone valerate (Beta-Val)

In a double-blind, parallel-group comparative trial, 84 patients with severe, localized plaque psoriasis were given halobetasol propionate 0.05% ointment or betamethasone valerate 0.1% ointment.¹⁶⁸ Halobetasol propionate proved significantly superior to betamethasone valerate with respect to the success rate, as indicated by ratings of "healed" or "marked improvement" (88.1 versus 64.3 percent; $p=0.02$). The therapeutic effect was observed within five days of the initiation of treatment in 76 and 67 percent of the patients treated with halobetasol propionate and betamethasone valerate, respectively. Both ointments were well tolerated.

hydrocortisone butyrate (Locoid), fluticasone dipropionate (Cutivate), prednicarbate (Dermatop), and mometasone furoate (Elocon)

A randomized, double-blind clinical trial involving 89 subjects with atopic dermatitis compared the safety, efficacy, and cosmetic acceptability of hydrocortisone butyrate 0.1% cream, fluticasone propionate 0.05% cream, prednicarbate 0.1% cream, and mometasone furoate 0.1% cream.¹⁶⁹ Treatments were self-administered twice daily for two weeks. Investigator ratings of signs and the patient ratings of signs and symptoms indicated comparable efficacy of all four treatments.

SUMMARY

Topical corticosteroids are effective in the treatment of dermatoses. Clinical data suggest that the efficacy of the topical corticosteroids is relative to their potency, but individual agents within a potency category are not distinguishable from each other. Once the disease is under control, it may be possible to decrease the frequency of application of these agents in order to avoid long-term adverse effects.

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